



AMERICAN PAIN FOUNDATION®

American Pain Foundation, Inc.
111 South Calvert Street, Suite 2700
Baltimore, MD 21202
Phone (410) 385-5276
Fax (410) 385-1832
www.painfoundation.org

May 22, 2001

Kimberly Topper
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: June 14-15 Meeting of the Anesthetic and Life Support Drugs Advisory
Committee Regarding Opiate Analgesics

Dear Ms. Topper:

Per the published notice in the May 3, 2001 Federal Register, **the American Pain Foundation requests 10 minutes to present oral testimony at the upcoming meeting of the Anesthetic and Life Support Drugs Advisory Committee on June 14 and 15 regarding opiate analgesics.**

The American Pain Foundation is an independent, non-profit information, education and advocacy organization serving people with pain. Our mission is to improve the quality of life for people with pain by raising public awareness, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management.

While there are several organizations that represent physicians, nurses and other health professionals who specialize in or practice pain management, only a handful speak solely for patients. The American Pain Foundation is the largest national nonprofit organization dedicated solely to representing the interests of consumers who suffer pain. (A list of our Board of Directors and Scientific Advisory Committee is attached.) As such we believe it is important for the FDA to hear not only from practitioners but also from the people who actually utilize regulated pain management therapies such as opioid analgesics.

Ms. Micke Brown, RN, BSN, a recognized expert in pain management, will present the organization's testimony. Ms. Brown's credentials include Pain Management Advisor for the American Pain Foundation; Pain Management Case Manager at Washington

Hospital Health Systems in Hagerstown, Maryland; Member of the Board of Directors of the Hospice of Washington County; Director at Large of the Executive Committee of the Hospice of Washington County; Public Policy Liaison for the American Society of Pain Management Nurses; Chair of the End-of-Life Task Force for the American Society of Pain Management Nurses; and former member of the Board of Directors for the American Society of Pain Management from 1998-2000. Ms. Brown also teaches pain management at Hagerstown Community College and Allegheny Community College.

The presentation will focus on the following four points:

1. Opioids can be lifesaving drugs for people with acute or chronic pain. The use of single-entity, long-acting, pure mu agonist drugs is appropriately growing as physicians and patients are learning that there is a broad, international consensus among pain experts that opioids, when appropriately prescribed, can be an effective treatment for moderate to severe pain, including non-malignant pain. Opioid drugs also are potentially abusable by those with addictive disorders. The public and the professional community acknowledge that careful regulation of these drugs is necessary to minimize the potential for diversion, misuse, abuse, and addiction. The American Pain Foundation strongly supports a balanced approach that explicitly protects the public's right to expanded access to appropriately prescribed opioid therapy while accepting measures that stem diversion and abuse.
2. Given the extraordinarily high prevalence of chronic pain disorders, the medical comorbidities of the patients with chronic pain, and the limited number of pain specialists in the U.S., the treatment of chronic pain must become part of primary care. It is the view of the American Pain Foundation that long-term opioid therapy is within the purview of generalist physicians because the risk of serious abuse or addiction among patients without known addictive disease is widely regarded to be very low and the principles of opioid pharmacotherapy are consistent with other types of treatments. Any regulatory policy that unduly restricts the use of legitimate opioid therapy by reducing the number of available drugs or limiting access to specific types of physicians is an unwarranted extreme response to concerns about diversion and abuse and establishes set a bad precedent.
3. Instead, better education of physicians, including general practitioners, and other health care professionals, is needed. Education on effective pain management is currently lacking among most such professionals. This education must include how to assess pain, utilize the proper pain management techniques, and identify and address signs of abuse, misuse and addiction.
4. Fear of unjustified regulatory scrutiny or investigation is one of the leading factors that causes health professionals to underutilize (or not utilize at all) opioids and other controlled substances under circumstances where they are medically appropriate. Additional regulatory barriers or hurdles can further impede access to medically justified treatment, both directly and by augmenting an existing "chilling effect".

We would greatly appreciate the opportunity to present the view of the consumer and patient on this important issue. For more information please contact me or Eileen Meier, Director of Government Affairs, at 202-262-7504. Ms. Micke Brown can be reached at 301 790-8533 or email of mickeab@starpower.net

Thank you for your consideration.

Sincerely,

John D. Giglio, M.A., J.D.
Executive Director

Att.

cc: M. Brown
E. Meier

Attachment

APF Board of Directors

Officers

Chairman: James Campbell, MD - Professor of Neurosurgery and Director of Blaustein Pain Treatment Center, Johns Hopkins Medical Center

Secretary: Kathleen Foley, MD – Attending Neurologist and former Co-Chief, Pain & Palliative Care Service, Memorial Sloan-Kettering Cancer Center

Treasurer: Martin Grabois, MD - Professor and Chairman, Department of Physical Medicine and Rehabilitation, Baylor College of Medicine

Additional Board Members

C. Richard Chapman, PhD - Director, Pain Research Group, Department of Anesthesiology, University of Utah School of Medicine

Charles Cleeland, PhD – McCullough Professor of Cancer Research and Director, Pain Research Group, MD Anderson Cancer Center

Robert Krughoff, JD - Founder and President of the Center for the Study of Services and Board member of the Consumer Federation of America

Russell Portenoy, MD - Chairman, Dept. of Pain Medicine and Palliative Care, and Medical Director, Jacob Perlow Hospice, Beth Israel Medical Center

Pamela Sutton, MD - Broward General Cancer Center, Parkland, Florida

APF Scientific Advisory Committee

Chair

Charles Cleeland, PhD – McCullough Professor of Cancer Research and Director, Pain Research Group, MD Anderson Cancer Center

Members

Lennette Benjamin, MD - Associate Professor of Medicine, Montefiore Medical Center

Charles Berde, MD - Co-founder and Director, Pain Treatment Service, Children's Hospital (Boston)

June Dahl, PhD - Professor of Pharmacology, University of Wisconsin-Madison Medical School, Chair of the American Alliance of Cancer Pain Initiatives

Gerald F. Gebhart, PhD - Professor and Chair, Dept. of Pharmacology, University of Iowa College of Medicine

Francis Keefe, PhD - Professor of Psychiatry, Duke University

Matthew Loscalzo, MSW - Director of Patient and Family Services, Johns Hopkins Oncology Center

Mitchell Max, MD - Chief, Clinical Trials Unit of NIDCR, National Institutes of Health

Christine Miaskowski, PhD, RN - Associate Professor and Chair, Department of Physiological Nursing, University of California at San Francisco